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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/561,345

12/20/2005

Udo Krupka

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22852

7590

06/11/2008

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EXAMINER

LUCAS, ZACHARIAH

ART UNIT

PAPER NUMBER

1648

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/561,345	<b>Applicant(s)</b> KRUPKA, UDO	
	<b>Examiner</b> Zachariah Lucas	<b>Art Unit</b> 1648	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 April 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 24-42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 24-42 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. Claims 24-42 are pending in the application.
2. The examiner to whom the case has been docketed in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Zachariah Lucas in Art Unit 1648.
3. It is noted that claim 31 refers to "positions of SEQ ID NO: 12." However, SEQ ID NO: 12 is only 154 residues in length, and claim 31 refers to positions 164 and 181 of SEQ ID NO: 12. Moreover, a comparison of the amino acids of claim 31 to SEQ ID NO: 12 does not match. Further, the specification indicates that these positions refer to positions of HBsAg, and not of SEQ ID NO: 12. See e.g., page 12, lines 22-29. It therefore appears that the Applicant intended to refer to the residues of SEQ ID NO: 12 corresponding to the indicated positions in the Hepatitis B virus surface antigen (i.e. the position numbers provided in the claims minus 42, e.g., position 115 is equivalent to position 73 of SEQ ID NO: 12).

Further, it is noted that both the claims and the specification refer to position 72 of SEQ ID NO: 12 as the corresponding residue to position 115 of HBsAg. However, the specification also indicates that this position should be an arginine which is found at position 73 of SEQ ID NO: 12. Moreover, a calculation of the position of SEQ ID NO: 12 corresponding to position 115 of HBsAg (115-42) indicates that position 73, and not 72, is correct position.

It is suggested that the specification and claims be amended accordingly.

***Election/Restrictions***

4. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 24-35, 40 (in part), 42, drawn to an HBV peptide and a first method of use.

Group II, claim(s) 36-38, 40 (in part), and 41, drawn to an anti-HBV antibody and a first method of use.

Group III, claim(s) 39, drawn to an antiidiotypic antibody representing an amino acid of HBsAg.

Group IV, claim(s) 40 (in part), drawn to an oligonucleotide encoding an HBV polypeptide.

Group V, claim(s) 40 (in part), drawn to a combination of at least 2 of an HBV peptide, oligonucleotide, and/or an anti-HBV antibody.

5. The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the common technical feature of the claimed inventions is a peptide comprising at 94% identity to SEQ ID NO: 13. Such a peptide is disclosed by Preisler-Adams et al. as described in the action mailed on October 31, 2007. The claims therefore lack a special technical feature over the prior art, and therefore also lack unity.

***Species Election***

6. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

**For any of Groups I-IV**, if elected, Applicant is required to elect one of the following peptides:

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- (a) SEQ ID NO: 19 (inclusive of SEQ ID NOs: 12-19) (claims 24-27, 29, 37),
- (b) SEQ ID NO: 22 (inclusive of SEQ ID NOs: 12-15, 18, and 20-22) (24-27, 29, 37), or
- (c) one residue, or a combination of residues, from those identified in claims 28 and/or 31.

**For Group V**, if elected, Applicant is required to elect:

a combination of at least 2 of the types of molecules of (i) peptides, (ii) oligonucleotides, and (iii) antibodies (claim 40); and

for each of the molecules of (i)-(iii) elected, to also elect one of (a)-(c) as described above with respect to Groups I-III.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

7. The claims are deemed to correspond to the species as indicated in the listing above.

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8. The following claim(s) are generic: Claims 28, 30-35, 40, and 42 for Group I. Claims 36, 38, and 40 for Group II. Claim 39 for Group III. Claim 40 for the species of Groups IV and V.

9. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: they lack a common special technical feature for the reasons indicated with respect to Groups I-V above.

### ***Conclusion***

10. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is (571)272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Zachariah Lucas/

Primary Examiner, Art Unit 1648